



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1039]

Nonclinical Evaluation of Endocrine-Related Drug Toxicity; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Nonclinical Evaluation of Endocrine-Related Drug Toxicity.” The purpose of this guidance is to clarify when additional studies are warranted after the standard toxicology tests have been conducted and there is a signal for potential adverse endocrine-related toxicity. This guidance finalizes the draft guidance entitled “Endocrine Disruption Potential of Drugs: Nonclinical Evaluation” issued on September 20, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Abby Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, rm. 6474, Silver Spring, MD 20993-0002, 301-796-0174.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Nonclinical Evaluation of Endocrine-Related Drug Toxicity.” This guidance focuses on nonclinical testing designed to assess the potential for a drug to cause endocrine effects that are unintentional and adverse. The standard comprehensive test battery is generally sufficient to identify endocrine-related toxicity. Depending on the outcome of a standard battery of nonclinical tests, additional nonclinical studies may be warranted to more fully characterize the endocrine-related toxicity potential of a drug.

This guidance finalizes the draft guidance entitled “Endocrine Disruption Potential of Drugs: Nonclinical Evaluation” issued on September 20, 2013 (78 FR 57859). Revisions to the draft guidance address public comments and try to give more clarity regarding when additional studies could be appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonclinical evaluation of endocrine-related drug toxicity. It does not establish any rights for any person and is not binding on FDA or the

public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-22683 Filed: 9/8/2015 08:45 am; Publication Date: 9/9/2015]